



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0115]

Agency Information Collection Activities; Proposed Collection; Comment Request;

Manufactured Food Regulatory Program Standards

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (the PRA), Federal Agencies are required to publish notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Manufactured Food Regulatory Program Standards.”

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE FEDERAL REGISTER].

ADDRESSES: Submit electronic comments on the collection of information to <http://www.regulations.gov>. Submit written comments on the collection of information to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT:

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SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the Federal Register concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) Whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information,

including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Manufactured Food Regulatory Program Standards--(OMB Control Number 0910-0601)--
Extension

In the Federal Register of July 20, 2006 (71 FR 41221), FDA announced the availability of a draft document entitled “Manufactured Food Regulatory Program Standards (MFRPS).” These draft program standards are the framework that States should use to design and manage its manufactured food program. The implementation of the standards will be negotiated as an option for payment under the State food contract. States that are awarded this option will receive up to \$25,000 over a period of 5 years to fully implement the program standards. Additionally, 26 States may receive up to \$300,000 each year for a period of 5 years to be in compliance with the 10 standards.

In the first year of implementing the program standards, the State program conducts a baseline self-assessment to determine if they meet the elements of each standard. The State program should use the worksheets and forms contained herein; however, it can use alternate forms that are equivalent. The State program maintains the documents and verifying records required for each standard. The information contained in the documents must be current and fit-for-use. If the State program fails to meet all program elements and documentation requirements of a standard, it develops a strategic plan which includes the following: (1) The individual element of documentation requirement of the standard that was not met; (2) improvements need

to meet the program element or documentation requirement of the standard; and (3) projected completion dates for each task.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden ¹

Respondent	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
State Departments of Agriculture or Health	44	1	44	303	13,332

¹There are no capital costs or operating and maintenance costs associated with this collection of information.

The burden has been calculated to 303 hours per respondent. This burden was determined by capturing the average amount of time for each respondent to assess the current state of the program and work toward implementation of each of the 10 standards contained in MFRPS. The hours per respondent will remain the same as implementation to account for continuing improvement and self-sufficiency in the program.

Dated: February 11, 2013.

Leslie Kux,

Assistant Commissioner for Policy.